



Novelos Therapeutics, Inc. (OTCBB: NVLT)

**Developing Novel Drugs for Treatment and Diagnosis of
Cancer**




January 30, 2012

DISCLAIMER

This slide presentation contains forward-looking statements. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement.

NOVELOS OVERVIEW

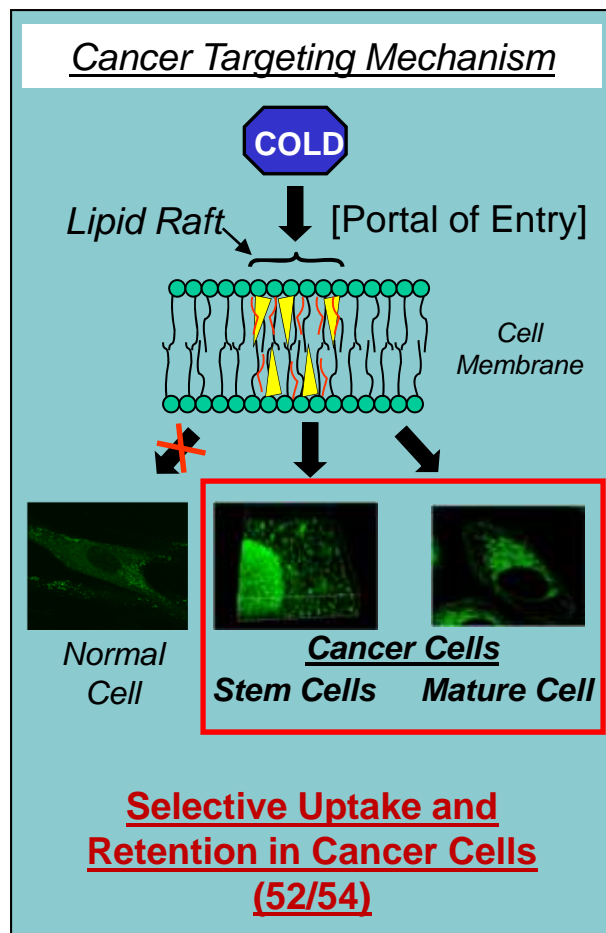
- ◆ Developing novel drugs for CANCER treatment & diagnosis
- ◆ Cancer-targeting technology: paradigm shift in cancer therapy and imaging
 - *Selective uptake, retention in cancer and cancer stem cells – avoid harm to normal cells*
 - Yields multiple distinct oncology product opportunities with alkyl phospholipids (APLs)

COMPOUND / APPLICATION	STAGE OF DEVELOPMENT					
	Preclin	IND	Phase 1	Phase 2	Phase 3	NDA
¹²⁴I-CLR1404 "LIGHT": Cancer Imaging Diagnosis of Solid Tumors						
¹³¹I-CLR1404 "HOT": Molecular Radiotherapy Solid Tumors (initially)						
CLR1404 "COLD": Akt-inhibiting Chemo Solid & Liquid Tumors						

- ◆ Experienced and proven management team and directors with combined 250+ years of life sciences expertise
- ◆ Near-term clinical development milestones

“LIGHT”, “HOT”, “COLD”

Novel, Cancer-Targeting, Broad Spectrum, Multi-Product Technology Platform



Cancer-targeted Radiopharmaceuticals

<u>Imaging</u>	<u>Therapy</u>
“LIGHT”	“HOT”
<ul style="list-style-type: none"> • First-in-Class Potential • FIND. TREAT. FOLLOW.™ • Phase 1-2 and Ph1b Trials Ongoing 	

Cancer-targeted Chemotherapy

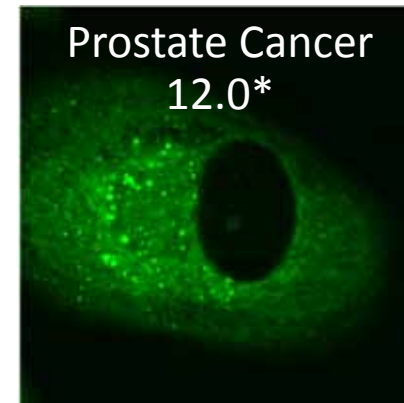
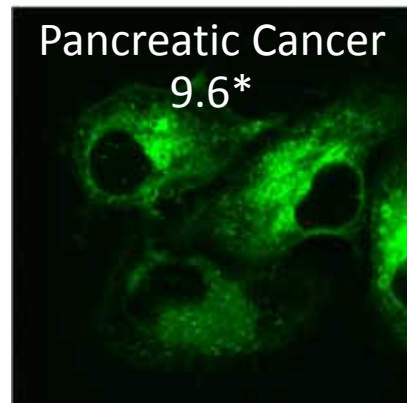
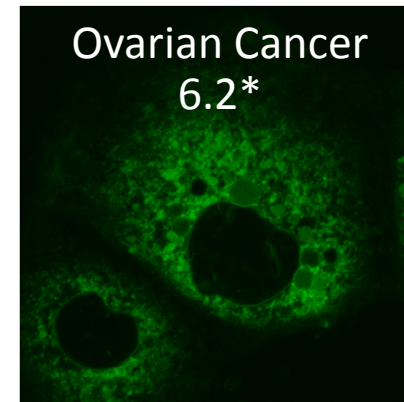
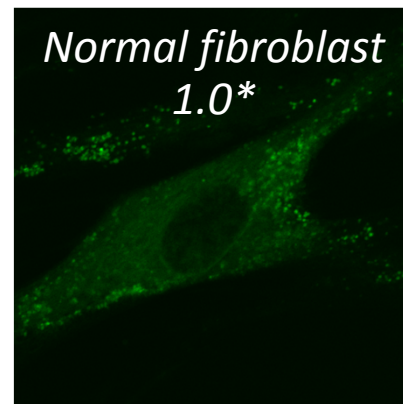
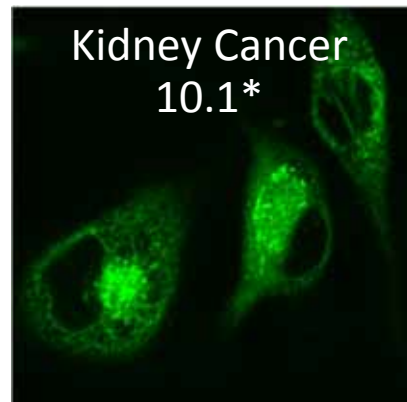
Monotherapy or Combination w/ Chemotherapy or Radiation

“COLD”

Akt

- Potential for Best-in-Class vs. Perifosine (KERX, AEZS)
- IND Planned Q1 2013

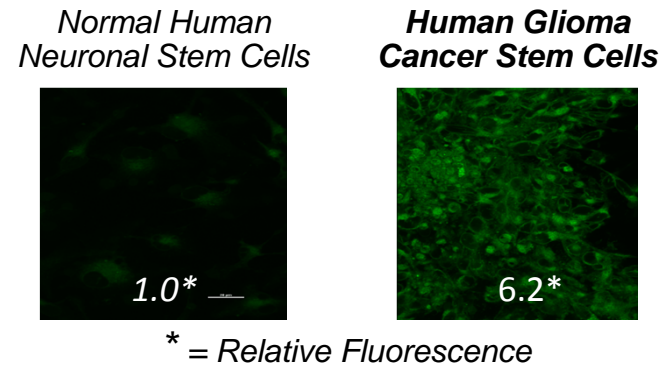
“LIGHT” / “HOT” / “COLD” Selectively Target a Wide Range of Cancer Cells



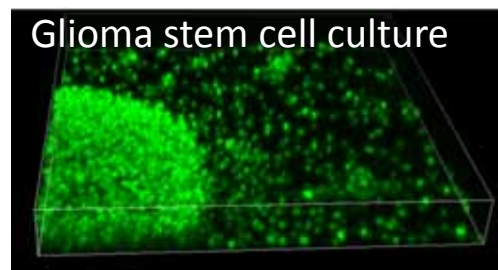
Cells labeled with fluorescent **COLD**; * fluorescent signal normalized to normal fibroblast (=1.0)

“LIGHT” / “HOT” / “COLD” Also Selectively Target Cancer Stem Cells

- ◆ Cancer stem cells
 - Drive tumor growth, metastasis
 - Resistant to chemotherapy, radiotherapy
 - Responsible for **cancer relapse**



- ◆ Our technology first to demonstrate targeting of cancer stem cells *in vitro* and *in vivo*
- ◆ Thus, **HOT** and **COLD** may result in **much longer disease-free status**

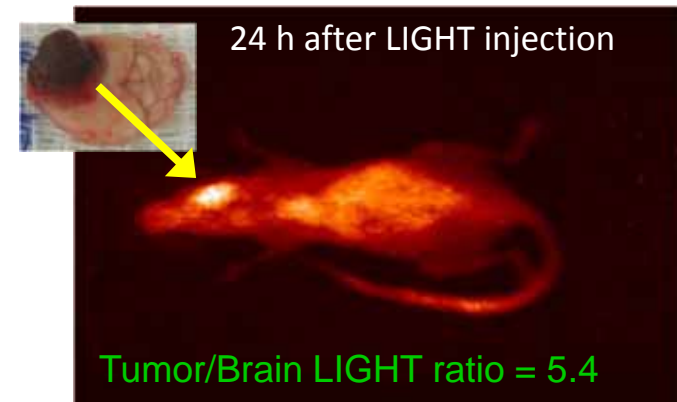


Labeled with fluorescent **COLD**

Implant glioma stem cells into mouse



PET imaging with **LIGHT**



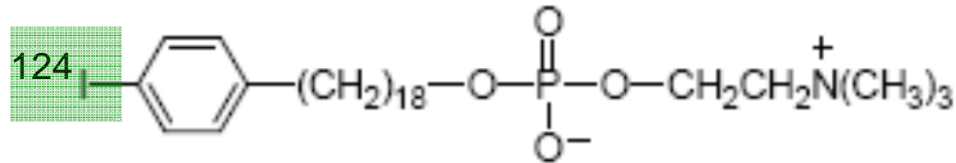
(Glioma stem cells re-isolated from tumor and grown in culture for 3 weeks still showed **label** retention)

“HOT” / “COLD” Represent a Paradigm Shift in Cancer Therapy

- ◆ The potential for efficacy vs. all three major drivers of mortality in cancer – primary tumors, metastases and stem cell-based relapse -- distinguishes **HOT/COLD** from all other cancer therapy modalities

	Primary Tumors	Metastases	Relapse
HOT / COLD	Treats	Treats	Prevents
<i>Non-specific Chemotherapy</i>	Treats	Treats	n/a
<i>Molecular Targeted Chemotherapy</i>	Treats	Treats	n/a
<i>Surgery</i>	Treats	Does not treat	n/a
<i>External Radiation</i>	Treats	Does not treat	n/a

“LIGHT”



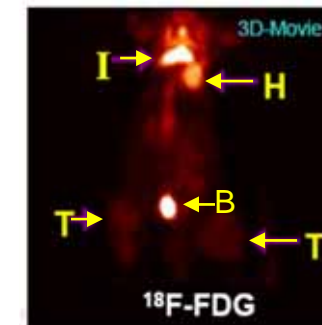
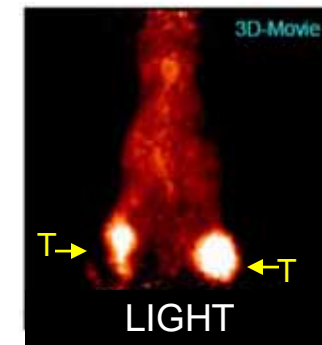
- ◆ **LIGHT** is potentially a first-in-class small molecule imaging agent that illuminates cancerous tumors and metastasis
- ◆ **LIGHT** = small, non-pharmacologic amount of **COLD** as a cancer-targeting delivery & retention vehicle + iodine-124 (a novel PET imaging isotope)
- ◆ Broad spectrum: selectively illuminated tumors in 52/54 preclinical *in vivo* (animal) cancer models
- ◆ **LIGHT** has two important uses
 - Cancer-selective PET imaging agent
 - Pre-therapy (“FIND”): diagnosis, staging, tumor baseline
 - Post-therapy (“FOLLOW”): evaluate therapeutic efficacy
 - Accelerate development of **HOT**
 - Predictor of efficacy
 - Calculate effective dose for Phase 2 trials
- ◆ **Investigator-sponsored Phase 1-2 trials ongoing; initial data Q2 2012**
 - Brain mets (NCI funded), lung cancer, other solid tumors (Q2 2012)

“LIGHT”

New “Gold Standard” for PET Imaging

- ◆ PET/CT imaging with 18-fluoro-deoxyglucose (FDG) (>\$500mil/year) is current state-of-the-art
- ◆ **LIGHT offers significant advantages:**

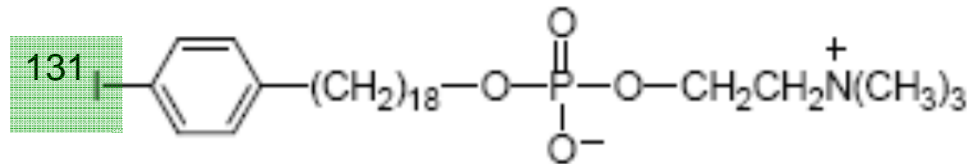
	LIGHT	FDG
Specificity	Cancer-specific	Not cancer-specific <i>(labels any high metabolic rate tissue)</i>
Spectrum	+++	++
Logistics of use	Can be used distant from production site (4 day $t_{1/2}$)	Must be used close to site of production (110 min $t_{1/2}$)
Cost	Similar	



Mouse Xenograft Model

T = Tumor, B = Bladder
I = Inflammation site, H = Heart

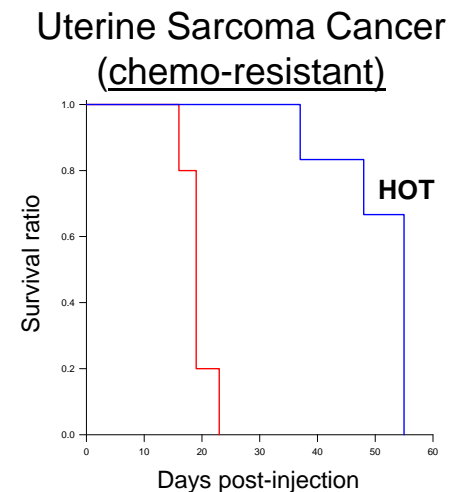
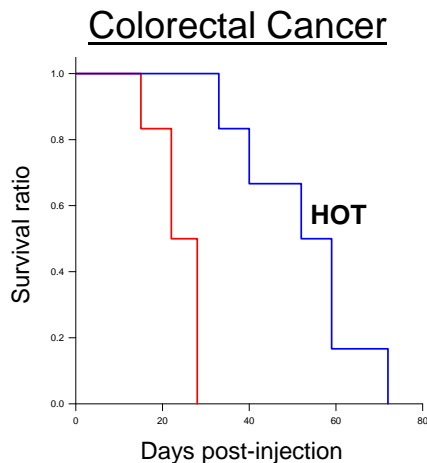
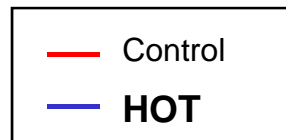
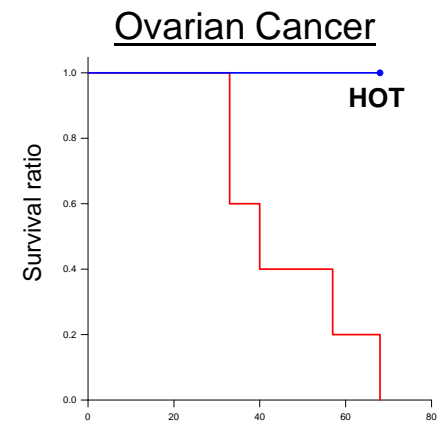
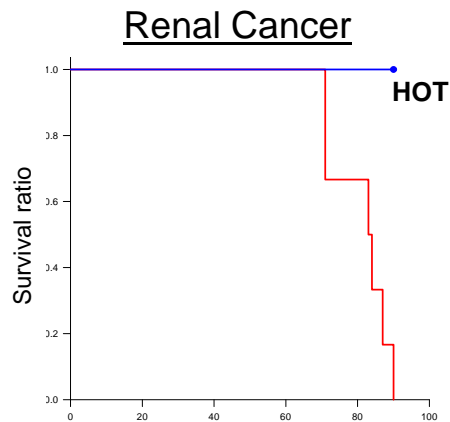
“HOT”



- ◆ **HOT** is potentially a first-in-class small molecule, broad-spectrum, cancer-targeted radiotherapeutic drug
- ◆ **HOT** = small, non-pharmacologic amount of **COLD** as cancer-targeting delivery and retention vehicle + cytotoxic radiotherapy (iodine-131)
- ◆ Preclinical data demonstrates remarkable killing of cancer cells coupled with excellent safety profile
 - “Intracellular radiation” mechanism provides broad-spectrum cancer killing
 - A single dose may be sufficient in some cancers
- ◆ US IND open – Phase 1a dosimetry trial successfully completed
- ◆ **Phase 1b dose-escalation trial ongoing**; Phase 2s starting in Q1 2013
- ◆ Develop **HOT** as monotherapy, initially for solid tumors with significant unmet medical need

“HOT”

Highly Efficacious in Mouse Xenograft Models

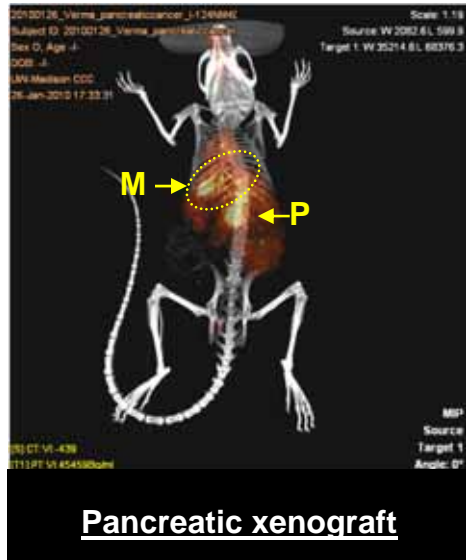


A **single dose*** of **HOT** (100 uCi, i.v.) was administered (Day 0) after tumors became established. Control = delivery vehicle; an equivalent, non-pharmacological dose of **COLD** (0.19 mg/kg)

* Two doses, one week apart for uterine sarcoma model

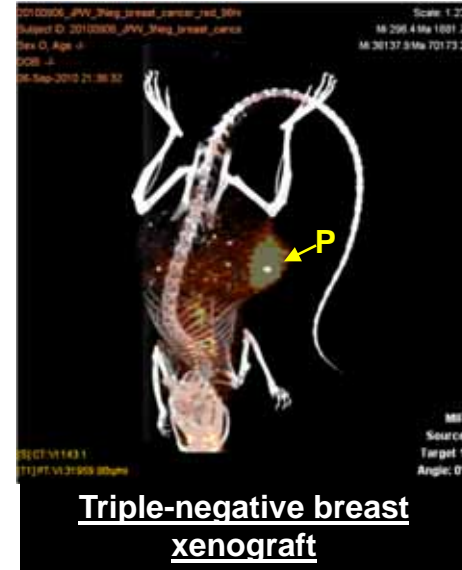
“HOT”

Selectively Taken Up/Retained in Malignant Tumors In Vivo

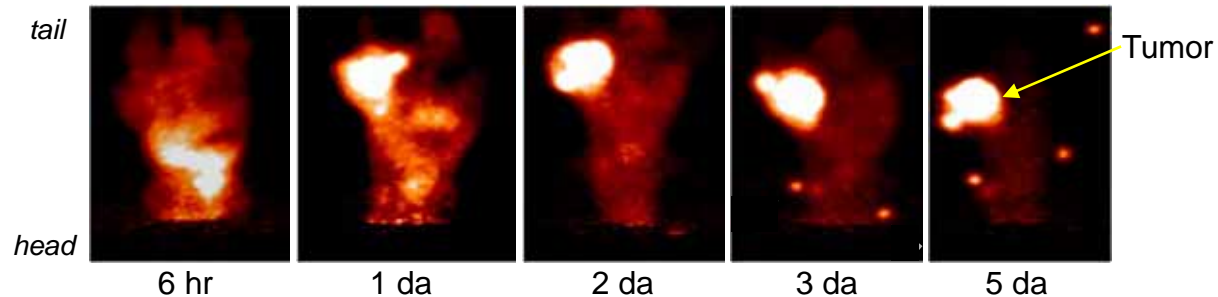


← PET/CT images →

48h post- i.v. **LIGHT**
P = primary tumor
M = metastases



Prolonged Tumor Retention
Prostate cancer xenograft

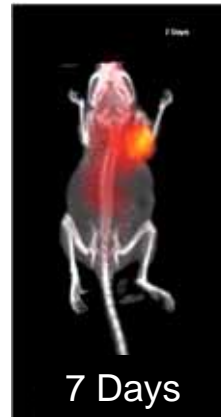
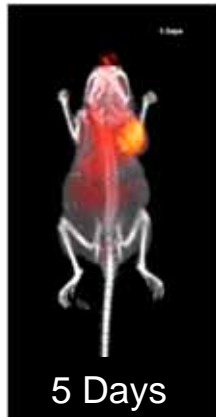
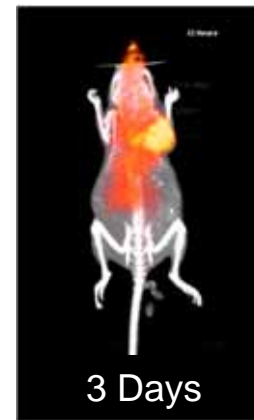


μPET imaging time course post- i.v. **LIGHT**

“HOT”

A Single Dose Induces Tumor Regression “*Find.Treat.Follow*”™

Human colon tumor xenograft model with established, 1 cm tumor. Tumor “disappears” over 9 days after a single injection of **HOT** (co-injected with **LIGHT** for imaging)



* time post-injection

FIND. TREAT. FOLLOW.™

Novelos

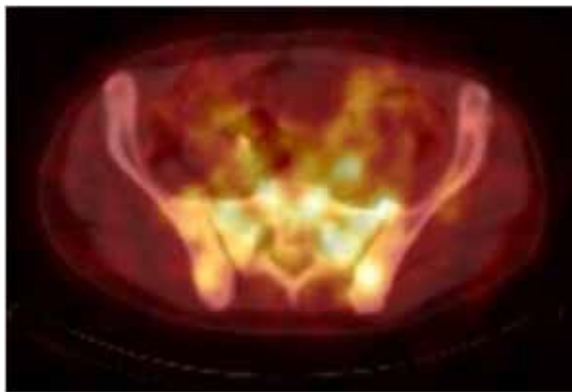
“HOT”

Targets Tumors in Human Cancer Patients

- ◆ Two subjects (one with colorectal cancer metastasized to lung and another with prostate cancer) had tumors that were imaged with 3D nuclear scanning (SPECT/CT) on day 6 after administration of **HOT** (10 mCi; sub-efficacious)
- ◆ Uptake of **HOT** into tumor tissue (but not adjacent normal tissue or bone marrow) was clearly demonstrated in both subjects

Patient 402 -- Prostate Cancer

Metastases in lumbar spine, pelvis, sacrum



Patient 301 -- Colorectal Cancer

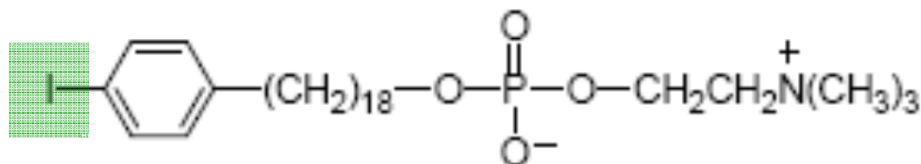
Metastases near the heart



“HOT” Clinical Development

- ◆ Successfully completed Phase 1a dosimetry trial in Feb 2010
 - Single i.v. doses of 10 mCi **HOT** in 8 patients with relapsed or refractory advanced solid tumors
 - Well tolerated - no SAEs reported; all AEs were considered minimal, manageable and not dose limiting
 - Limited tumor imaging plus analysis of total body imaging and urine samples collected over 42 days indicated that **HOT** reached target cancer lesions and that exposure was sustained
 - Sites: Georgetown, Johns Hopkins, Duke, City of Hope
- ◆ **Phase 1b dose-escalation / MTD trial ongoing**
 - Initial dose of 12.5 mCi / m² (~20 mCi); 0.6 mg total mass of **COLD**
- ◆ Initiate Phase 2s in Q1 2013 upon response in Phase 1b and / or calculation of minimal efficacious dose from ongoing **LIGHT** imaging trials
 - NSCLC, triple-negative breast cancer, brain mets, soft tissue sarcoma, etc.

“COLD” - THERAPEUTIC

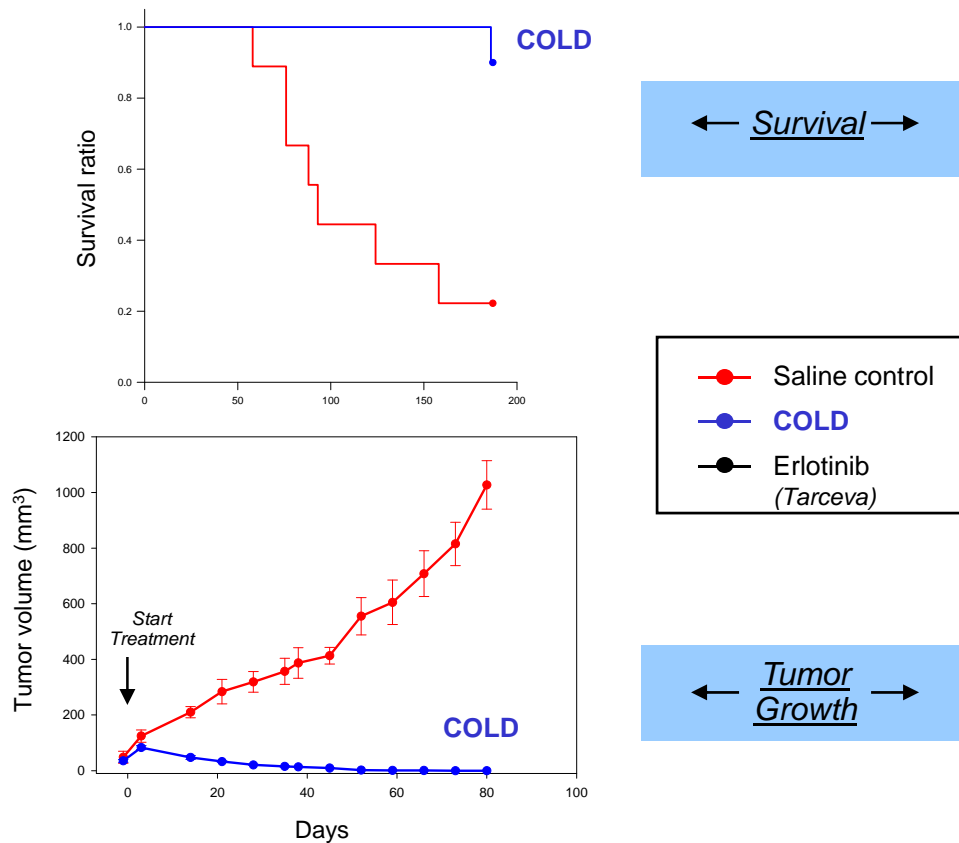


- ◆ **COLD** is a novel small molecule Akt inhibitor – alkyl phospholipid (APL) – cancer-targeted chemotherapy
 - **Selectively taken up and retained by cancer cells vs. normal cells**
- ◆ **COLD** potential for best-in-class vs perifosine (KERX+AEZS = \$400mil market cap)
- ◆ Perifosine in Phase 3 trials under SPAs in combo with chemo in colorectal cancer and multiple myeloma
- ◆ Perifosine efficacy is capped by dose-limiting GI side effects stemming from its oral route of administration; cannot be given i.v. due to hemolysis
- ◆ **COLD significant ADVANTAGE: i.v. administration offers potential for greater efficacy AND safety vs. perifosine**
- ◆ IND submission planned Q1 2013

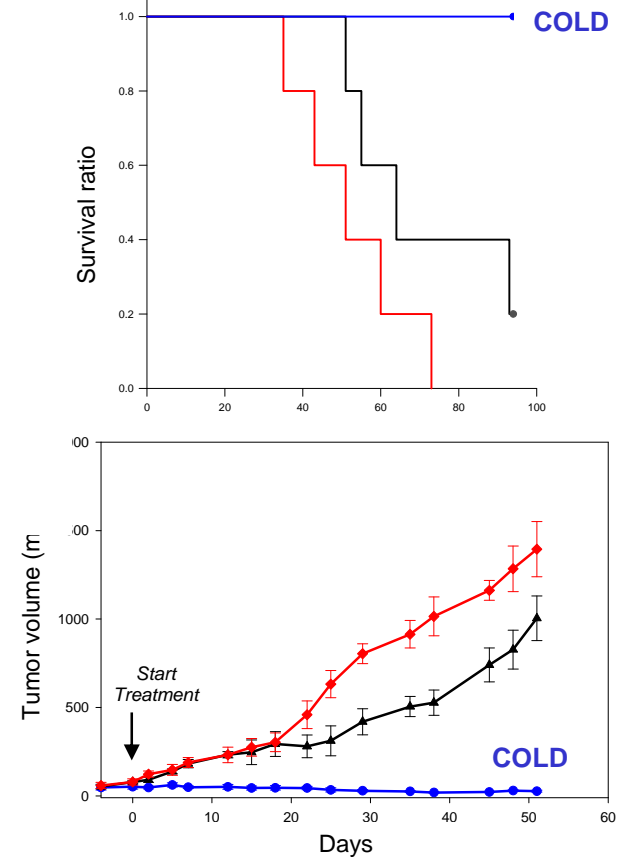
“COLD” - THERAPEUTIC

Highly Efficacious in Mouse Xenograft Models

Triple-Negative Breast Cancer



Non-Small Cell Lung Cancer



COLD monotherapy in mouse xenograft models. Treatment started on Day 0, after tumors became established.
COLD 19 mg/kg, i.v. weekly x 5 wk. Erlotinib 12.5 mg/kg, i.p. daily for 3.5 wk. Saline i.v. weekly x 5 wk.

MILESTONES

Novel Cancer-Targeted Technology	1Q12	2Q12	3Q12	4Q12	1Q13	2Q13
"LIGHT": Cancer-Targeted PET Imaging						
Phase 1-2 in Brain Mets - Initial Data Q2 2012		L				
Phase 1-2 in Lung Cancer - Initial Data Q2 2012		L				
Phase 1-2s in Other Solid Tumors - FPI Q2 2012			L			
"HOT": Cancer-Targeted Radiotherapy						
Phase 1b - Ongoing						
Phase 2a in Lung Cancer or Brain Mets - FPI Q1 2013						H
Phase 2a in Other Solid Tumors - FPI Q2 2013						
"COLD": Cancer-Targeted Chemo (Akt Inhibitor)						
IND Submission - Q1 2013					IND	
Additional Peer Reviewed Publications - Q2 2012						

L = **LIGHT** initial imaging clinical data expected (*establish HOT Phase 2a dose; drive partner interest*)

H = **HOT** Phase 2a initial efficacy signal expected (*proof of concept*)

FINANCIALS

- ◆ Funding into Q3 2012
 - \$5.5mil cash projected at Dec 31, 2011
 - \$9.5mil stockholder equity projected at Dec 31, 2011
- ◆ Capitalization
 - 37mil shares of common stock
 - 59mil shares fully diluted
- ◆ \$37mil invested to-date in development of our APLs
 - Investors include:
 - Fundamental life sciences institutional investors
 - Radiologists and oncologists

SENIOR MANAGEMENT

- ◆ **Harry Palmin, President and CEO, Director**
 - Head of Novelos for 13 years; previously at Lehman Brothers and Morgan Stanley...
- ◆ **Jamey Weichert, Ph.D, Chief Scientific Officer, Technology Founder, Director**
 - 25 years of imaging & radiotherapy design, inventor of Novelos' cancer-targeted tech, Associate Professor Dept Radiology and Medical Physics at U Wisconsin, Madison...
- ◆ **Chris Pazoles, Ph.D, SVP of Research & Development**
 - 30 years of biopharmaceutical R&D and senior management experience, including Pfizer and Abbott...
- ◆ **Kim Hawkins, VP of Clinical Development**
 - 17 years of clinical operations and senior management experience, including Boston Medical, Genzyme, Antigenics...
- ◆ **Joanne Protano, VP and Chief Financial Officer**
 - 20 years of finance and senior management experience, including public companies and Deloitte & Touche...
- ◆ **J. Patrick Genn, VP of Investor Relations**
 - 30 years banking, investment and senior management, including Wells Fargo...

INDEPENDENT DIRECTORS

- ◆ **Stephen Hill, B.M. B.Ch., M.A., F.R.C.S., Chairman**
 - CEO 21CB; former CEO of Solvay Pharmaceuticals USA; 25+ years of expertise in biopharmaceutical senior management, product development, commercialization and partnering; formerly CEO of ArQule and Head of Global Drug Development at Roche...
- ◆ **Thomas Rockwell Mackie, Ph.D., Director**
 - Co-founder, Chairman and Director of Research of TomoTherapy (NASDAQ: TOMO); leading figure in the field of radiation therapy; full professor Dept of Medical Physics and Human Oncology at the University of Wisconsin-Madison...
- ◆ **James Manuso, Ph.D., Director**
 - CEO of Astex (NASDAQ: ASTX); 30+ years of expertise in life sciences senior management, product commercialization, partnering, financing, venture and consulting...
- ◆ **John Neis, CFA, Director**
 - Managing Director of Venture Investors LLC, heads Healthcare practice; 23 years in venture capital, serving on boards of lifesciences companies from formation through IPO or sale. ...
- ◆ **John Niederhuber, M.D., Director**
 - Nationally renowned surgeon and researcher who has dedicated his four-decade career to the treatment and study of cancer - as a professor, director of National Cancer Institute (2005-2010), National Cancer Advisory Board chair, grant reviewer, and investigator...
- ◆ **Howard Schneider, Director**
 - 35 years experience as senior financial industry executive...
- ◆ **Michael F. Tweedle, Ph.D., Director**
 - Professor Cancer Imaging in Radiology at Ohio State; 30+ years expertise in imaging and diagnostics, senior research and management; former President of Bracco Research USA, head of diagnostics at BMS...

KEY CONSULTANTS

◆ **Michael Kurman, M.D., Medical Oncology Consultant**

- Medical oncologist; 30 years expertise in oncology clinical development; successfully developed / launched 4 products...

◆ **Minesh Mehta, M.D., FASTRO, Radiation Oncology Consultant**

- Professor of radiation oncology at Northwestern Univ.; preeminent radiation oncologist with 25+ years expertise; 100+ cancer clinical trials and ~500 publications / abstracts...

◆ **Joanne Mortimer, M.D., FACP., Medical Oncology Consultant**

- Admin. Director of Phase 1 Programs, and Vice-Chair and Professor, Medical Oncology and Therapeutics Research, City of Hope Comprehensive Cancer Center; served on FDA Oncology Drug Advisory Committee...

◆ **Robert Shepard, M.D., FACP., Medical Oncology Consultant**

- Medical oncologist; 25+ years expertise in oncology clinical development; PI for ~30 pharma oncology trials...

◆ **Kenneth Tew, Ph.D., D.Sc, Cellular/Molecular Oncology Consultant**

- Professor and Chair, Dept. of Cell and Molecular Pharmacol. & Expt'l. Therapeutics, Medical University of South Carolina; Fox Chase; 25+ years expertise in cancer molecular biochemistry and pharmacology including cancer cell signaling pathways...

◆ **Richard Wahl, M.D., Radiation Oncology Consultant**

- Professor and Director Nuclear Medicine / PET Center and Vice-Chair for Technology and Business Development at Johns Hopkins University; instrumental in development and commercialization of Bexxar...

INVESTMENT CONSIDERATIONS

- ◆ Novel cancer-targeting small molecule technology based on selective uptake and retention in cancer and cancer stem cells – **paradigm shift in cancer therapy and imaging**
 - **LIGHT**: potentially new “gold standard” for PET imaging -- out-licensing opportunity following Phase 1-2 trials – FDG market \$1B by 2017
 - **HOT**: potentially first-in-class cancer-targeted radiotherapeutic – remarkable killing of cancerous tumors with excellent safety profile
 - Bayer \$800mil global licensing deal with Algeta (Sept 2009) for prostate bone mets indication
 - Favorable reimbursement change for radiotherapeutics
 - **COLD**: Akt inhibitor – best-in-class potential vs. perifosine (KERX+AEZS = \$400mil market cap)
- ◆ Experienced and proven management team and directors with combined 250+ years of life sciences expertise
- ◆ In-house cGMP radiopharmaceutical manufacturing facility in Madison, WI
- ◆ Global cancer market ~\$80B by 2012; US cancer care cost \$158B by 2020
- ◆ Broad IP portfolio

Appendix

Intellectual Property

◆ LIGHT

- Composition of matter US 2016+
- Method of use, EU expiry **2025+**; US, Japan, etc pending
- Method of manufacture US 2028+

◆ HOT

- Composition of matter US 2016+
- Method of use, EU expiry **2025+**; US, Japan, etc pending
- Method of manufacture US 2028+

◆ COLD

- Method of use applications; US, PCT; potential expiry **2030+**

Intellectual Property (*Expected Expiry Dates*)

Key Claims	COLD	HOT	LIGHT
Composition of matter	---	US Granted (2016+)	US Granted (2016+)
Use <i>(cancer therapy)</i>	US, PCT Pending (2030+)	EU Granted US, ROW Pending (2025+)	EU Granted US, ROW Pending (2025+)
Use <i>(Cancer stem cell- based therapy)</i>	---	US/PCT Pending (2030+)	---
Manufacture	---	US Granted (2028+)	US Granted (2028+)
Imaging	---	---	US, EU Pending (2025+)

MANUFACTURING

In-house cGMP Radiopharmaceutical Manufacturing Facility

- cGMP manufacturing facility
- Reliability for **HOT** dosimetry dose demonstrated
- Reliability for **HOT** therapy dose demonstrated
- Exceptionally high radiochemical purity
- **HOT** CMC meets NDA standards *today*
- Terminally sterilized
- **HOT** shipped as a patient ready dose
- **HOT** shipped at ambient temperature
- Very stable
- We can already manufacture at scale
- Low cost of goods



NOVELOS OBJECTIVES

- ◆ **“LIGHT”** Phase 1-2 imaging trials initial data expected Q2 2012 (brain mets and lung cancer); other solid tumors trial starting Q2 2012
 - First-in-class potential
 - Partnering opportunity upon initial data from Phase 1-2 trials
 - Predictor of efficacy and driver of **HOT** Phase 2 trials
- ◆ **“HOT”** Phase 1b MTD trial ongoing in patients with solid tumors; Phase 2s expected to start Q1 2013
 - First-in-class potential, broad-spectrum, cancer-targeted radiotherapeutic
- ◆ **“COLD”** IND submission planned Q1 2013
 - Best-in-class potential vs. perifosine (KERX+AEZS = \$400mil market cap)